REMARKS

Claims 21, 24, and 30 have been amended. Claims 32 and 35 have been cancelled. Claims 1-3, 10-21, 24-26, 28, and 30, 31, 33, 34, and 36-40 are presented for the Examiner's review and consideration. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Claim Objections

Claim 21 was objected to because of an informality. Claim 21 has been amended to address this typographic error.

Rejection under 35 U.S.C. §102(b)

Claims 1-3, 10, 11, 18-20, 30, 32-35, and 37 were rejected under 35 U.S.C. §102(b) as being anticipated by Li (U.S. Patent No. 5,505,735; hereinafter "Li"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Li

Li discloses a surgical anchor and method for using the same. Surgical anchor 12 comprises a body 14 having a longitudinal axis 15, a front end 16, a front portion 18 adjacent front end 16, a rear end 20, and a rear portion 22 adjacent rear end 20. The outer surface 24 of front portion 18 tapers gradually toward longitudinal axis 15 as it approaches front end 16. This provides body 14 with a generally forwardly pointed configuration. Rear portion 22 includes an outer surface 25. A bore 26 extends through front portion 18, perpendicular to longitudinal axis 15. Bore 26 is sized such that a strong suture 28, or some other suitable anchor pulling means, may be connected thereto for pulling anchor 12 in a forward axial direction.

The anchor's rear portion 22 includes an opening 30 extending transversely through body 14 adjacent its rear end 20. Opening 30 is preferably, but not necessarily, oriented substantially parallel to bore 26 in front portion 18. Opening 30 is sized to receive a loop of ligament, tendon or the like, or a loop of suture which is in turn attached to a ligament, tendon or the like, or a

loop of suture which is in turn attached to a bone block or plug, so as to attach the desired repair material to the anchor.

A plurality of barbs 36 extend outwardly and rearwardly from body 14, in spaced circumferential relation to each other. In an embodiment, one such barb 36 extends outwardly and rearwardly from the forward end 35 of each channel 34. Barbs 36 are formed out of an elastically deformable material such that outer ends 38 can be forced radially inwardly so as to be located within the periphery of an axial projection of the maximum geometric cross-section of body 14. On account of this construction, when an anchor 12 is inserted longitudinally into an appropriately sized bone tunnel, the outer ends 38 of barbs 36 will engage, and be deflected inwardly by, the side wall of the bone tunnel. This yieldable engagement of barbs 36 with the adjacent bone permits the anchor to be moved along the bone tunnel and then fixed securely in position.

Instant Invention

The instant invention provides an implant for securing a suture relative to a body tissue (hard and/or soft) in a patient's body. The implant includes a body portion and a pointed end portion. The body portion is movable through an opening in the body tissue and has a longitudinal central axis and a maximum transverse length transverse to the longitudinal central axis. The body portion includes a first passage extending therethrough transverse to the longitudinal central axis (of the body portion). A suture may be threaded through this first passage. The pointed end portion is connected with the body portion along the longitudinal central axis and is operable for piercing the body tissue. The pointed end portion has a maximum transverse length transverse to the longitudinal central axis no greater than the maximum transverse length of the body portion. Thus, the implant has a pointed end portion that is no wider than the body portion. The implant may further include a second passage formed through both the body portion and the pointed end portion. The second passage is also transverse to the longitudinal central axis of the body portion. A suture may be threaded through the second passage or through both the first and second passages. *See*, for example, paragraphs **[0006]-[0011]**; **[0013]**; **[0014]**; **[0022]**; **[0030]-[0034]**; **[0046]**; and **[0184]-[0190]** and Figures 1, 2, and 11 of the published application.

Argument

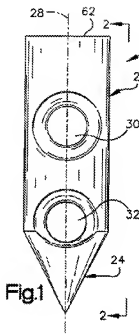

Fig.1

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). *See* MPEP 2131.

Claim 1 of the instant application recites that "said body portion and said end portion having a second passage formed therethrough transverse to the longitudinal central axis and transversing said body portion and said end portion for threading the suture therethrough." Similarly, claim 30 recites "said passage is formed in said body portion and said pointed portion." These features of claims 1 and 30 are evident from Figure 1 of the instant application which shows passage 32 traversing through body portion 22 and end portion 24.

In prior Office Actions, the interpretation of how the prior art allegedly met these elements of the claims was presented. In some cases, this was in the form of an annotated drawing from the prior art. In the outstanding Office Action, this is not done. Applicant respectfully submits that the reason for this is that bore 26 of Li is completely located within front portion 18 of Li. As shown in the drawings from Li shown to the right, the vertical dotted line of Figure 3 is located within front portion 18 and bore 26 is in front of this line. Even if the vertical

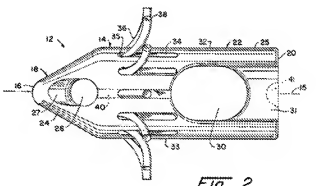

Fig. 2

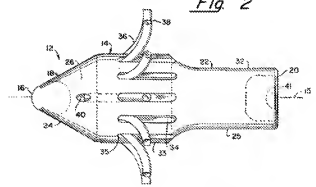

Fig. 3

dotted line divides the tapering front portion 18 from the cylindrical portion, the dotted line is tangent to bore 26. In other words, bore 26 is located entirely within front portion 18.

Accordingly, Li does not teach each and every element of the invention, as currently claimed, in independent claims 1 and 30, as is required to establish anticipation under 35 U.S.C. §102(b). Thus, independent claims 1 and 30 are not anticipated by Li. As claims 2, 3, 10, 11, and 18-20 depend from claim 1 and claims 31, 33, 34, and 36 depend from claim 30, these dependent claims necessarily include all the elements of their base claims. Thus, Applicant respectfully submits that the dependent claims are allowable over Li for at least the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b).

Rejections under 35 U.S.C. §103(a)

Claims 12-17, 21, 26, and 36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Li. Claim 24 was rejected under 35 U.S.C. §103(a) as being unpatentable over Li in view of Schwartz et al. (U.S. Patent 6,306,159 B1; hereinafter "Schwartz") and Hayhurst (U.S. Patent 4,741,330; hereinafter "Hayhurst"). Claim 25 was rejected under 35 U.S.C. §103(a) as being unpatentable over Li in view of Schwartz, Hayhurst, and Egan (U.S. Patent 6,106,545; hereinafter "Egan"). Claim 28 was rejected under 35 U.S.C. §103(a) as being unpatentable over Li in view of Schwartz, Hayhurst, and Huxel et al. (U.S. Patent 6,503,259 B2; hereinafter "Huxel"). Claim 31 was rejected under 35 U.S.C. §103(a) as being unpatentable over Li in view of Whittaker et al. (U.S. Patent 5,417,712; hereinafter "Whittaker"). Claim 38 was rejected under 35 U.S.C. §103(a) as being unpatentable over Li in view of Hayhurst. Claim 39 was rejected under 35 U.S.C. §103(a) as being unpatentable over Li in view of Schwartz, Hayhurst, and Egan. Claim 40 was rejected under 35 U.S.C. §103(a) as being unpatentable over Li in view of Schwartz.

For reasons set forth below, Applicant respectfully submits that all of these rejections should be withdrawn.

It is noted that the references are described separately only in order to clarify what each reference teaches and not to argue the references separately.

The teachings of Li are applied as above. Further, Applicant notes that Schwartz, Hayhurst, Egan, Huxel, and Whittaker have been discussed extensively in previously-filed Responses. These discussions are incorporated herein by reference.

Schwartz

Schwartz discloses a device (and methods for deploying and using the device) for repairing a soft tissue defect, particularly a defect in the meniscus of the knee. *See* abstract and column 1, lines 9-15. The device includes an outer wall anchor and an inner menicscal anchor; the outer wall anchor for engaging against an outside wall of the meniscus on a first side of a defect and the inner meniscal anchor for engaging an inner surface of the meniscus on a second side of a defect. The device also includes a suture which adjustably connects the anchors together. Tension on the suture pulls the anchors together to close the defect and a locking mechanism locks the suture in place. *See* abstract; column 1, lines 28-32; and column 4, lines 1-13. The outer wall anchor can be longitudinally shaped and have one or more holes through which sutures may pass freely. The inner anchor is shaped to resist movement once deployed and may be cannulated to allow for sliding of the suture. When the device is deployed, the suture loops through the holes in the outer anchor and both ends of the suture traverse back through the cannula of the inner anchor. When the suture is tensioned the outer wall flips into place to provide support for the outer wall. *See* column 1, lines 34-41.

Hayhurst

Hayhurst discloses a method and apparatus for anchoring and manipulating cartilage and other fibrous tissue within a joint during arthroscopic surgery. *See* abstract; column 1, lines 10-16; and column 2, lines 5-17. Generally, the apparatus includes a hollow tube, hollow needle, an anchoring device, and a suture. The hollow needle has open ends (tip and butt) and is associated with the hollow tube which is of equal or greater length than the needle. The tube fits movably within the needle. The anchoring device is deformed from its elongate shape within the tip of the hollow needle and the suture is attached thereto. In preparation for use, the free end of the

suture is passed through the bore of the needle and the tube and extends through the butt of the needle. The anchoring device is then lodged into the tip of the needle by pulling on the suture. *See* abstract and column 2, lines 18-50. The needle is then used to pierce the cartilage and the tube is used to expel the anchoring device behind the cartilage to be anchored. The anchor then returns to its original shape. The needle and tube are then removed from the joint. The cartilage can then be secured, manipulated, and/or removed by application of tension to the suture. *See* abstract; column 2, line 56 to column 3, line 22; and Figure 1. Additionally, in one embodiment Hayhurst discloses permanent attachment of tissue with the suture/anchoring device. The exterior of this anchoring device has barb-like projections to anchor it in a hole drilled for that purpose. A retainer can be used to maintain tension in the suture and is slidable along the suture in one direction and resists movement in the opposite direction to hold the tissue securely in place. *See* abstract; column 3, lines 23-35; column 8, lines 1-38; and Figures 10-14 and 17.

Egan

Egan discloses a suture tensioning and fixation device used for fastening of tissues. The device includes a suture thread and a suture retainer. The retainer has a first suture thread engaging a portion on the first end, a second suture thread engaging a portion opposite the first suture thread, and a third substantially centrally located suture thread. The retainer is adapted such that the segments of thread can be interwoven between the suture-engaging portions of the retainer and frictionally held. *See* abstract; column 1, lines 40-56; and Figure 1. The retainer and the suture thread can be bonded together under application of energy, such as thermal or ultrasonic energy, which melts the retainer material thus fixing the suture thread in place when cooled. *See* column 1, lines 57-67; column 2, lines 29-30; column 3, lines 19-45; and Figure 5.

Huxel

Huxel discloses a fastener and method for performing anastomosis (re-connection of severed ends of tubular organs). *See* column 1, lines 5-8. The apparatus is a fastener including a plurality of individual fastener pairs each having a piercing element with a pin that pierces the tissue to be repaired and a receiver portion that interlocks with the pin of the corresponding piercing element. A fastener dispenser is also disclosed that holds the piercing elements and

receiver elements in juxtaposition and in a predetermined geometric configuration, such as a circle. In use, the tissues to be joined are positioned between the piercing elements and the receiving elements held in the dispenser. The dispenser then ejects the piercing elements and pushes them through the tissue and into the receiving elements causing the elements to interlock (piercing elements with the receiving elements) and capture the tissue there between. Since the fastener includes a plurality of individual fasteners, flexibility is maintained to allow for radial expansion of an organ such as that which occurs during peristalsis in the intestines. *See* abstract column 2, lines 1-27; and Figure 1.

Whittaker

Whittaker discloses an improved anchoring device for anchoring objects to bone. *See* abstract and column 1, lines 5-12. The device has a fastening means which permits the anchor to be fastened within a bone hole/tunnel while minimizing the stress on the body of the anchor during installation. *See* abstract and column 2, lines 52-60. The device includes a body, attachment for attaching the desired object to the body, and fastening means for fastening the anchor within a bone hole/tunnel. The body is divided into three portions; distal, middle, and proximate. The distal portion has a first end and a second end, the proximal portion also has a first end and a second end; and the middle portion extends from the second end of the distal portion to the first end of the proximal portion. The attachment may include a round or elongate hole extending diametrically through a portion of the body. The fastening means includes a curved central portion and multiple bone-engaging elements. Each of the bone-engaging elements is connected to the central portion and extends outwardly from the anchor body. *See* column 3, lines 17-44. The bone-engaging elements are cantilevered to the curved central portion such that during anchor insertion the stress generated by deformation of the fastening means is supported by the curved central portion. *See* column 8, lines 23-30. The device is capable of being deployed by any known anchor installation methods. *See* column 3, lines 5-7 and 45-47. The device can be made from polymeric or biodegradable materials and can be manufactured using both conventional polymer molding technology and metal-forming technology. *See* abstract; column 2, lines 48-51; and column 3, lines 1-4, 8-10.

Instant Invention

The instant invention is as applied above further including an implant assembly wherein the body portion is defined as "cylindrical" and the pointed end portion described as "more rigid than the body tissue." In addition to the implant, the assembly includes a suture extending through the first and second passages and a suture retainer. The retainer has a first configuration and a second configuration. In the first configuration it is freely slidable along the suture and in the second configuration it is secured and connected to the suture maintaining the tension therein. *See* paragraphs **[0030]**; **[0032]**; and **[0063]-[0074]** and Figure 4 of the published application.

Argument

Applicant respectfully submits that the combination of the teachings of Li with any or all of the teachings of the cited secondary references (Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker) does not obviate the invention as currently claimed.

Independent claims 1 and 30 recite, *inter alia*, an implant for securing a suture relative to a body tissue (hard and/or soft) in a patient's body. The implant includes a body portion and a pointed end portion. The body portion is movable through an opening in the body tissue and has a longitudinal central axis and a maximum transverse length transverse to the longitudinal central axis. The body portion includes a first passage extending there through transverse to the longitudinal central axis (of the body portion). A suture may be threaded through this first passage. The pointed end portion is connected with the body portion along the longitudinal central axis and is operable for piercing the body tissue. The pointed end portion has a maximum transverse length transverse to the longitudinal central axis no greater than the maximum transverse length of the body portion. Thus, the implant has a pointed end portion that is no wider than the body portion. The implant may further include a second passage formed through both the body portion and the pointed end portion. The second passage is also transverse to the longitudinal central axis of the body portion. A suture may be threaded through the second passage or through both the first and second passages.

Independent claim 24 recites, *inter alia,* an implant assembly including an implant, a suture, and a retainer. The implant is similar to that which is recited in claims 1 and 30, having a

body portion defined as "cylindrical" and a pointed end portion described as "more rigid than the body tissue." In the claimed assembly the suture extends through the first and second passages and can be tensioned. The retainer has a first configuration and a second configuration; in the first configuration it is freely slidable along the suture and in the second configuration it is secured and connected to the suture maintaining tension therein.

By rejecting these claims under 35 U.S.C. §103(a), the Examiner asserts that the claimed invention is merely an obvious combination of known elements.

Applicant respectfully disagrees and submits that all of the elements of the implant/implant assembly, as currently claimed, are not found in the prior art and further, even if all elements could be gleaned from the prior art, there is no motivation or suggestion to combine these elements.

First, with regard to claims 12-17, 21, and 26, all dependent on claim 1, the Examiner asserts that it would have been obvious to one of ordinary skill in the art to use any of allogenic, autogenic, xenogenic, cortical bone, single piece of freeze dried bone, metal, metal alloy, biodegradable material, and/or bioerodible material in either soft tissue or bone with the device of Li since it was known in the art that these materials are used with suture devices with soft tissue or bone.

Applicant respectfully disagrees. Regardless, as established above, Li does not teach each and every element of the implant as currently claimed in claim 1. Thus, even if one were to use any of these materials with the device of Li, one would not be using the claimed implant or implant assembly.

With regard to claims 24, 25, 28, 39, 40 rejected over Li in view of Schwartz, *inter alia*, the Examiner asserts the following regarding the teachings of Schwartz:
*"Schwartz teaches a suture **40** being passed through and extending through first **24** and second **26** passages and being threaded through said first passage and said second passage, wherein the suture is operative to rotate an anchor **20** when under tension, and a retainer connected to the suture for maintaining tension in the suture (Figures 4-7; abstract; column 2, lines 14-16)."*

Applicant respectfully submits that the Examiner's analysis of Schwartz is incomplete. While Schwartz discloses several different embodiments for securing the sutures (column 5, lines 1-2 and Figures 6-13), a retainer for maintaining tension on the sutures is not mentioned.

With regard to claims 24, 25, 28, 38, and 39 rejected over Li in view of Schwartz and further in view of Hayhurst, *inter alia*, the Examiner asserts the following regarding the teachings of Hayhurst:

*"Hayhurst teaches a retainer **68** having a first configuration in which the retainer is freely slidable along the suture and a second configuration in which the retainer is secured and connected to the suture for maintaining the tension in the suture (see abstract, Figures 13-14, column 8, lines 25-32)."*

Applicant respectfully disagrees with the Examiner's interpretation. The retainer disclosed by Hayhurst is movable along the suture in one direction only. *See* abstract and column 3, lines 28-31.

With regard to claims 25 and 39 rejected over Li in view of Schwartz, Hayhurst, and Egan the Examiner asserts the following regarding the teachings of Egan:

*"Egan teaches a retainer **24** connected to a suture **22** that is made of a material that becomes flowable when ultrasonic vibratory energy is applied so that no knot is required to fix the suture in place (column 3, lines 5-30)."*

Applicant does not disagree that Egan teaches bonding a retainer and a suture together with application of ultrasonic vibratory energy, however Egan does not remedy the deficiencies of Li, Schwartz, and Hayhurst as he does not provide or suggest the missing elements such that his disclosure (Egan) can be combined (with Li, Schwartz, and Hayhurst) to result with the implant assembly as currently claimed. Thus, even if one were to use ultrasonic vibratory energy with a device derived from a combination of the teachings of Li, Schwartz, and Hayhurst, one would not be using the claimed implant assembly.

With regard to claim 28 rejected over Li in view of Schwartz, Hayhurst, and Huxel the Examiner asserts the following regarding the teachings of Huxel:

*"Huxel teaches a force distribution member **16** being disposed between a retainer and body tissue (Figure 8)."*

Applicant respectfully disagrees. Gasket **16** is interposed between elements **12** and **14** (piercing and receiving elements) of the fastener array **10**. *See* column 2, lines 60-67 and Figures 1 and 8. Thus, contrary to the Examiner's assertion, element **16** is not disposed between a retainer and body tissue.

With regard to claim 31 rejected over Li in view of Whittaker the Examiner asserts the following regarding the teachings of Whittaker:

"Whittaker teaches that a suture passage may extend at an acute angle to the longitudinal axis, such as in Figures 13 and 16.The passage ("central portion") extending at an angle may facilitate deformation of a suture ***12*** *(column 8, lines 28-30)."*

Applicant respectfully disagrees. The suture passages disclosed by Whittaker are designated as element **33** and each extends longitudinally along the outer surface of the body **6** of anchor **3**. Thus, contrary to the Examiner's assertion, the suture passages do not extend at acute angles to the longitudinal axis, but rather are parallel to this axis. Bone-engaging means **45** are shown as extending at an acute angle to the longitudinal axis. Furthermore, central portion **42** is a part of the bone-engaging means and not a suture passage. *See* column 6, lines 49-62; column 8, lines 1-33; and Figures 1 and 13.

Accordingly, based upon the above, it is clear that all of the elements of the claimed implant/implant assembly can not be found in the combination of the teachings of Li with the teachings of any or all of the cited secondary references (Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker).

Furthermore, even if one of ordinary skill in the art were to interpret the combination of the teachings of Li with any or all of Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker as disclosing all of the elements of the invention as claimed, the fact that each reference discloses a part of the invention such that all references together disclose all parts of the claimed invention does not, in and of itself, render the invention an obvious combination of the references.

"The question under 35 USC 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made." In re Lamberti, 545 F.2d at 750, 192 USPQ at 280 CCPA 1976.

In addition to what is suggested by the combination of references, an Examiner must provide clear articulation of the reasons for his/her finding of obviousness. *See* MPEP 2142.

"Rejections based on obviousness cannot be sustained by mere conclusory statements, instead there must be some articulated reasoning with some rational underpinning to support the

legal conclusion of obviousness." See MPEP 2141 III; *KSR International Co. v. Teleflex, Inc.* 550 US 398 (2007); 82 USPQ2d 1396.

Why would one of ordinary skill in the art be motivated to combine the teachings of Li with any or all of the teachings of Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker? The Examiner provides only vague generalizations in support of motivation and/or suggestion to combine the references such as "it is known in the art" and "to promote healing." The mere fact that something is known does not automatically give one reason to apply the knowledge. And the "promotion of healing" can be a goal of any surgical technique. Are there specific suggestions in the references to combine? What suggestion is made in the references that the combination of teachings would promote healing? Do the secondary references (Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker) suggest improvements for a device such as that disclosed by Li? Without answers to these questions, the Examiner's statements regarding obviousness are merely unsupported conclusions and thus, insufficient to support a *prima facie* case of obviousness.

Based on both the above discussion of the teachings of the cited references and the above discussion of motivation/suggestion, Applicant respectfully submits that the combined patents (Li with Schwartz, Hayhurst, Egan, Huxel, and Whittaker) do not teach all of the elements of the invention as currently claimed and thus, they (the combined patents) can not possibly suggest that their combination produces the claimed implant/implant assembly. Thus, motivation to combine is non-existent.

Based upon all of the above arguments, it is clear that neither the cited patents (Li with Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker) nor any other prior art teach or suggest an implant or an implant assembly as currently claimed.

Accordingly, Applicant submits that independent claims 1, 24, and 30 are patentable over Li in view of Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker. As claims 2, 3, 10-21, and 26 depend from claim 1; claims 25 and 28 depend from claim 24; and claims 31, 33, 34, and 36-40 depend from claim 30, these dependent claims necessarily include all the elements of their base claims. Thus, Applicant respectfully submits that these dependent claims are allowable over Li in view of Schwartz, Hayhurst, Egan, Huxel, and/or Whittaker at least for the same reasons.

In light of all of the foregoing arguments, Applicant respectfully requests reconsideration and withdrawal of all rejections of claims under 35 U.S.C. §103(a).

Conclusion

In light of the foregoing amendments and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned. A fee for a two month extension of time is believed to be due and is being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-003-1).

Respectfully submitted,

/ Paul D. Bianco /

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